MAR 2 9 2001

Attachment 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Troponin I method for ADVIA® IMS™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010291

1. Intended Use

This *in vitro* diagnostic method is intended to quantitatively measure the concentration of cardiac Troponin I (TnI) in human serum and plasma (lithium heparin) using the Bayer ADVIA IMS system. When used in conjunction with other clinical data, such as presenting symptoms and diagnostic procedures, measurement of cardiac Troponin I aids in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with non-ST segment-elevation, acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 Troponin I	T01-3887-51	T03-3888-01

3. Device / Method

Product Name	Reagent Part #	BAN	Calibrator Part #	BAN
ADVIA® IMS™ Troponin I	B42-3920-22	06120626	B43-3947-01	06956201

Minumum Detectable Conc.

Method	ADVIA	Immuno 1
MDC	0.05 ng/mL	0.05 ng/mL

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
0.46	5.3
0.65	3.7
1.93	3.2
7.19	1.9
51.89	1.8

Immuno 1	
Level (ng/mL)	Total CV(%)
0.61	4.7
0.79	4.1
2.9	3.3
6.9	2.3
47.4	2.0

Correlation (Y=ADVIA IMS, X=comparison system)

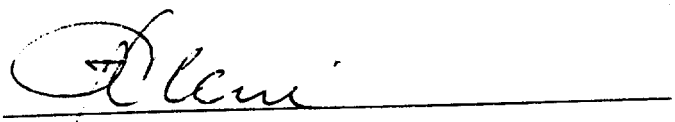
Specimen type	Comparison System (X)	N	Regression Equation	Syx ng/mL	R	Sample Range (ng/mL)
Serum	Immumo 1	50	Y=1.02 - 0.01	0.03	0.998	0.05 – 2.34
Serum	Immuno 1	59	Y=0.96 + 0.26	0.47	0.999	0.05 – 70.10
Plasma	Immuno 1	52	Y=0.98 - 0.24	0.34	0.999	0.05 – 45.93

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Troponin I Conc (ng/mL)	Effect (% change)
Bilirubin	25	6.08	-0.3
Hemoglobin	1000	7.14	-4.5
Urea Nitrogen	200	6.20	-1.6
Lipids (Triglycerides)	1000	6.15	0.5
Creatinine	2.5	6.20	-1.6
Albumin	6.5	5.69	-0.5

Analytical Range

Serum/Plasma: 0.05 to 200 ng/mL or 0.05 to 200 µg/L



1/15/01

Director ~~Manager~~ Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 9 2001

Mr. Fredrick Clerie
Director Regulatory Affairs
Bayer Corporation
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: K010201
Trade Name: ADVIA® IMS™ Troponin I Assay
Regulatory Class: II
Product Code: MMI
Dated: January 18, 2001
Received: January 22, 2001

Dear Mr. Clerie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010201

Device Name: **ADVIA® IMS™ Troponin I Assay**

Indication For Use:

This *in vitro* diagnostic method is intended to quantitatively measure the concentration of cardiac Troponin I (TnI) in human serum and plasma (lithium heparin) using the Bayer ADVIA IMS system. When used in conjunction with other clinical data, such as presenting symptoms and diagnostic procedures, measurements of cardiac TnI aids in the diagnosis of a cute myocardial infarction (AMI) and in the risk stratification of patients with non-ST segment-elevation, acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.

This diagnostic method is not intended for use on any other system.

Ellen Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010201

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Optional Formal 1-2-96